UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ENZO BIOCHEM, INC. ET AL.	:	
Plaintiffs,	:	
vs.	:	02-CV-8448 (RJS)
AMERSHAM PLC, et al.	:	
Defendants,	:	
AND RELATED CASES NAMING	:	
MOLECULAR PROBES, INC., PERKINELMER, INC., PERKINELMER LIFE SCIENCES, INC., ORCHID BIOSCIENCES, INC., AFFYMETRIX, INC., ROCHE DIAGNOSTICS GMBH, AND ROCHE MOLECULAR SYSTEMS, INC. AS DEFENDANTS AND/OR DECLARATORY JUDGMENT PLAINTIFFS	:	03-CV-03817 (RJS) 03-CV-03819 (RJS) 03-CV-03816 (RJS) 04-CV-01555 (RJS) 04-CV-04046 (RJS) 03-CV-08907 (RJS)
and	:	
YALE UNIVERSITY	:	
Nominal Defendants.	:	

DEFENDANTS' JOINT STATEMENT PURSUANT TO LOCAL RULE 56.1

Pursuant to Rule 56.1 of the Local Rules of the United States District Court for the Southern District of New York, Amersham plc and Amersham Biosciences, Molecular Probes, Inc., PerkinElmer Life Sciences, Inc., PerkinElmer, Inc., Orchid Biosciences, Affymetrix, Inc. and Roche Diagnostics GmbH and Roche Molecular Systems, Inc. submit the following statement of material facts as to which there is no genuine issue to be tried.

I. UNDISPUTED FACTS RELATING TO NON-INFRINGEMENT OF PATENTS

A. The Ward Patents

1. 824 claim 1,'767 claim 42: products with directly detectable labels do not satisfy the "A limitation"

1. Claim 1 of the '824 patent and claim 42 of the '767 patent require that "A ... represents at least one component of a signaling moiety capable of producing a detectable signal."

2. The Court has ruled that A is "one component of a multi-component signaling moiety capable of indirect detection via an attached polypeptide." (Ex. 16, Claim Construction Order at 9-10, 23.)

3. The Court rejected Enzo's argument that the claimed A group "could be the sole component of a signaling moiety and therefore operate alone as a directly detectable label." (Ex. 16, Claim Construction Order at 9-10.)

4. The accused products of Exhibit 23 all include, or result in, a directly detectable fluorescent group attached, through a chemical group, to a nucleotide or, in some instances, a polynucleotide. (Ex. 24, Burczak Decl. ¶¶ 11, 26, 30, 33, 34, 37, 38, 43, 45, 48, 50; Ex. 25, Mayer Decl. ¶¶ 20-21; Ex. 26, Singer Decl. ¶¶ 19-20.)

5. For each accused product of Exhibit 23, the fluorescent label operates alone and without the addition of other chemical groups to produce a directly detectable signal and thus is not "one component of a multi-component signaling moiety." (Ex. 24, Burczak Decl. ¶¶ 33, 37, 45, 50, 55; Ex. 25, Mayer Decl. ¶ 21; Ex. 26 Singer Decl. ¶ 21.)

6. The accused products of Exhibit 23 are not designed to be detected indirectly "via an attached polypeptide." (Ex. 24, Burczak Decl. ¶¶ 33, 37,45, 50, 55; Ex. 25, Mayer Decl. ¶ 21; Ex. 26, Singer Decl. ¶ 21.)

7. The function of the fluorescent labels of the accused products of Exhibit 23 is to provide a directly detectable signal. (Ex. 27, Blackburn SJ Decl. ¶¶ 143-145.)

8. The function of the claimed A group is to form a stable complex with a detectable polypeptide. (Ex. 27, Blackburn SJ Decl. ¶¶ 143-145.)

9. To provide a directly detectable signal, the fluorescent labels of the accused products of Exhibit 1 absorb excitation light at one wavelength and emit fluorescent light at another. (Ex. 27, Blackburn SJ Decl. ¶¶ 143-145.)

10. To achieve its function, the claimed A group engages in a binding interaction with a polypeptide. (Ex. 27, Blackburn SJ Decl. ¶¶ 143-145.)

11. Enzo may allege for at least certain defendants that a small three-carbon group, which is part of a spacer between the fluorescent label and the nucleotide base, constitutes the claimed A group. The three-carbon group that Enzo identifies as the claimed A group is not even hypothetically capable of indirect detection via an attached polypeptide. (Ex. 27, Blackburn SJ Decl. ¶¶ 151-153.)

12. The function of the three-carbon group within the accused products of Exhibit 23 is to serve as part of the spacer that provides distance between the fluorescent dye and the nucleotide. (Ex. 27, Blackburn SJ Decl. ¶¶ 154-55.)

13. The three-carbon group of the accused products of Exhibit 23 achieves this function by providing a chemical linkage between the fluorescent dye and the nucleotide. (Ex. 27, Blackburn SJ Decl. ¶¶ 154-55.)

14. The three-carbon group of the accused products of Exhibit 1 results in increased distance between the fluorescent dye and the nucleotide. (Ex. 23, Blackburn SJ Decl. ¶¶ 154-55.)

2. 767 claim 42: products lacking a pentose sugar do not satisfy the "oligo- or polynucleotide" requirement.

15. Claim 42 of the '767 patent requires a "nucleotide" that includes a pentose sugar. (Ex. 16, Claim Construction Order at 6-8).

16. The accused AcycloPrime products of Exhibit 28 lack a pentose sugar. (Ex. 25, Mayer Decl. ¶17.)

17. During prosecution of application U.S.S.N. 255,223 (the original Ward application which led to the '767 patent), Enzo rebutted a §103 obviousness rejection by arguing "[t]hat the references (Bergstrom and Ruth) are only directed to pyrimidine nucleosides" (which differ from nucleotides in that they lack a phosphate group) and there "is absolutely no teaching or suggestion in any of these references of nucleotides or chemically labeled nucleotides, either pyrimidine nucleotides or purine nucleotides." (Ex. 29, Supp. Comm. filed 9/21/82 p. 3.)

18. During prosecution of application U.S.S.N. 255,223 (the original Ward application which led to the '767 patent), Enzo represented that "[i]t is not seen how one skilled in the art having the disclosures of these references in view would come away with any teaching or suggestion of applicants' claimed invention which is nucleotide-based." (Ex. 29, Supp. Comm. filed 9/21/82 p. 3.)

19. In parent application, U.S.S.N. 496,915, which matured into the '955 patent, Enzo distinguished the claimed subject matter over prior art references on the basis that the references "do not refer to or suggest applicants' nucleotides because they only refer to bases without sugars." (Ex. 30, Amdmt filed 6/25/85 at 26.)

3. '824 claim 1: dideoxynucleotides do not satisfy the 3' phosphate requirement

20. The claimed method of claim 1 of the '824 patent requires use of a compound with the depicted nucleic acid polymer structure. (Ex. 8, '824 patent col. 30:55-31:10.)

21. The claimed structure requires a phosphate group attached to the 3' position of the labeled nucleotide. (Ex. 27, Blackburn SJ Decl. ¶¶156.)

22. The accused products of Exhibit 34 do not have a 3' phosphate group because they are dideoxynucleotide monomers, which have a hydrogen atom at the 3' position. (Ex. 27, Blackburn SJ Decl. ¶157; Ex. 24, Burczak Decl. ¶24; Ex. 25, Mayer Decl. ¶25.)

23. When a dideoxynucleotide monomer is used to make a DNA polymer, the 3' hydrogen prevents another nucleotide, or any other chemical group, from being attached to the 3' polymer end. (Ex. 24, Burczak Decl. ¶24; Ex. 25, Mayer Decl. ¶26.)

24. Because they terminate DNA polymer growth, the accused labeled dideoxynucleotide monomers of Exhibit 34 are always the final nucleotide at that end. (Ex. 24, Burczak Decl., ¶24; Ex. 25, Mayer Decl., ¶25, 26.)

25. It is impossible for the products of Exhibit 34 to result in the structure with a phosphate group attached at the 3' position as required by the claim. (Ex. 27, Blackburn SJ Decl. ¶158.)

26. The 3' hydrogen atom of the accused products of Exhibit 34 prevents further extension of a DNA polymer making the products useful for the Sanger dideoxy sequencing method, whereas the 3' phosphate group required by the claim allows for farther polymer extension and cannot be used for such sequencing method. (Ex. 27, Blackburn SJ Decl. ¶¶158-59.)[1]

4. '824 claim 1, '767 claim 42: products without a nucleotide base attached to "A" cannot satisfy the claimed requirements.

27. Each Ward patent requires a nucleotide base "B," which is defined as a 7-deazapurine or pyrimidine moiety. (Ex. 8,'824 claim 1, Ex. 9, '767 claim 42)

[1] To the extent Enzo contends that PE's acycloterminator products infringe claim 1 of the '824 patent, they lack both a carbon at the '3 position of a pentose sugar and an attached phosphate at that position.

28. Roche's DIG 5' End Labeling Sets do not contain a nucleotide base B. (Ex. 32, Will Decl. ¶¶7-8.)

29. The asserted claims also require an "A" group attached to the nucleotide base B at a specified position. (Ex. 8,'824 claim 1, Ex. 9,'767 claim 42 (Ex. 34))

30. Roche's DIG 5' End Labeling Sets contain no nucleotide base B to which the A group must be attached.

31. When Roche's DIG 5' End Labeling Sets are used to label an oligonucleotide, the label is not attached to any base position, as required by the asserted Ward claims. (Ex. 32, Will Decl. ¶¶ 7-8.) Instead, the label is attached to the 5' end of the sugar.

32. A nucleotide base B is an entirely different and distinct structure from the pentose sugar structure found in a nucleotide. (Ex. 37, Blackburn SJ Decl. ¶17; Ex. 47, Testimony of Enzo's expert, Dr. Hammes, at *Markman* hearing, 7/6/05 Tr. at 163.)

33. During prosecution Enzo repeatedly emphasized the novelty of the attachment of the A group to not only a nucleotide base B, but to specific positions on the nucleotide base B, (Ex. 30, pp. 10:10-14, 27-30; 15:1-4; 18:26-19:17.)

B. THE '373 PATENT

1. The Required Format

34. Claim 1 of United States Patent No. 4,994,373 (the '"373 patent") recites "a method for detecting a polynucleotide sequence" that requires "fixing said polynucleotide sequence to a solid support" and "forming an entity comprising said polynucleotide sequence hybridized to a polynucleotide or oligonucleotide probe, said probe having attached thereto a chemical label." (Ex. 10,'373 patent col. 13:31-46; *see also* Ex. 16, Claim Construction Order at 20.)

35. The ’373 patent defines an “analyte” as “[a] substance . . .whose presence is to be detected and, if desired, quantitated.” (Ex. 10,’373 parent col. 1:27-34; *see also* Ex. 16, Claim Construction Order at 20.)

36. The ’373 patent defines “probe” as a “labeled polynucleotide or oligonucleotide sequence which is complementary to a polynucleotide or oligonucleotide sequence of a particular analyte and which hybridizes to said analyte sequence.” (Ex. 10,’373 patent col. 1:42-45 (Ex. 20); *see also* Ex. 16, Claim Construction Order at 19-20.)

37. Claim 1 of the ’373 patent - and all of the remaining asserted claims, which all depend from claim 1 - require a test format whereby “the sample, which is the substance within which one is looking for the analyte, must be fixed to the solid support, and the probe, which is a labeled sequence complementary to the analyte, cannot be so fixed.” (Ex. 16, Claim Construction Order at 20, 24, 18 n.21.)

38. Claim 1 of the ’373 patent - and all of the remaining asserted claims, which all depend from claim 1 - “require[] that the probe be labeled.” (Ex. 16, Claim Construction Order at 20, 18 n.21.)

39. The accused products of Exhibit 35 do not include or result in a sample fixed to a solid support. (Ex. 36, McGall Decl. ¶4; Ex. 32, Will Decl. ¶3; Ex. 25, Burczak Decl., ¶20, 21, 39, 44, 47, 49; Ex. 25, Mayer Decl. ¶10.)

40. In each of the accused products of Exhibit 35, the probe (and not the sample) is fixed (Ex. 36, McGall Decl. ¶¶4, 6; Ex. 32, Will Decl. ¶3; Ex. 24, Burczak Decl., ¶21, 32, 44, 49; Ex. 25, Mayer Decl., ¶ 30)

41. The accused products of Exhibit 35 do not include or result in a labeled probe. (Ex. 36, McGall Decl. ¶¶4, 7; Ex. 32, Will Decl. ¶3; Ex. 24, Burczak Decl., ¶121, 32, 44, 49; Ex. 25, Mayer Decl. ¶ 31)

42. Because the '373 patent requires that the probe be labeled, it would be impossible to conduct tests with the probe fixed to the solid support, since to do so would result in false positives. (Ex. 16, Claim Construction Order at 20, *citing* hearing testimony of Dr. George Stark; *see also* Ex. 36, McGall Decl. ¶10)

43. The configuration of the accused array products of Exhibit 35 - unlabeled probe attached to solid support, and labeled analyte free-floating before hybridization - enhances mass production and enables complicated experiments that would not be possible using the format claimed in the '373 patent. (Ex. 36, McGall Decl. ¶¶9, 11)

2. The Required Soluble Signal

44. Claim 1 of the '373 patent - and all of the remaining asserted claims, which all depend from claim 1 - require generation of a "soluble signal." (Ex. 10, '373 patent col. 13:44-46; *see also* Ex. 16, Claim Construction Order at 20-21, 18 n.21.)

45. Claim 1 of the '373 patent - and all of the remaining asserted claims, which all depend from claim 1 - require in their use of "soluble signal," the creation of a soluble, or uniformly dispersed, product which generates a detectable signal. (Ex. 16, Claim Construction Order at 24, 18 n.21.)

46. The accused products of Exhibit 35 do not use or result in a "soluble signal" - *i.e.,* they do not create a soluble, or uniformly dispersed, product which generates a detectable signal, (Ex. 36, McGall Decl. ¶¶1 3-14; Ex. 32, Will Decl. ¶¶4-5; Ex. 24, Burczak Decl., ¶31,43, 48; Ex. 25, Mayer Decl. ¶¶33; *see also* Ex. 16, Claim Construction Order at 24, 20-22; Ex. 37, Perkins Decl. ¶31.)

47. The accused products of Exhibit 35 utilize a tethered fluorescent molecule that is not dissolved or in a solution. (Ex. 36, McGall Decl., ¶¶13-14; Ex. 32, Will Decl., ¶¶4-5; Ex. 24, Burczak Decl. ¶31,43,48; Ex. 25, Mayer Decl, ¶33; *see also* Ex. 16, Claim Construction Order at 22; Ex. 37, Perkins Decl. ¶27.)

48. The non-soluble signals utilized by the accused products of Exhibit 35 allow users of those products to pinpoint the location of a hybridized sequence, whereas the soluble signal of '373 claim 1 does not, because it is uniformly dispersed. (Ex. 36, McGall Decl. ¶14; Ex. 32, Will Decl. ¶5; Ex. 24, Burczak Decl., ¶31, 43, 48; Ex. 16, Claim Construction Order at 24, 20-22; Ex. 37, Perkins Decl. ¶27.)

II. DISTRIBUTOR AGREEMENTS BAR ENZO'S PATENT INFRINGEMENT CLAIMS AGAINST PRODUCTS ON WHICH ENZO WAS PAID

A. Enzo's Agreement With Roche

49. Roche had a written agreement with Enzo entitled "Distribution and Supply Agreement" that took effect in 1994 and granted it rights to distribute and sell certain products notwithstanding Enzo patents. (Ex. 41, Enzo's First Amended Answer and Counterclaims ("ECC") ¶49.)

50. Roche was authorized by the 1994 distribution agreement with Enzo to distribute and sell to the research market certain "PRODUCTS" - *i.e.,* products "covered by" certain Enzo patents. (Ex. 41, Enzo's First Amended Answer and Counterclaims ("ECC") 49; *see also* Ex. 40, Roche Agreement at 1, App. A.)

51. Roche distributed and sold products as it was authorized. (Ex. 42, Togonal Decl. ¶4-6.)

52. Roche continuously made payments to Enzo under the distribution agreement on 13 of the products accused of infringing. (Ex. 42, Togonal Decl. ¶ 4.)

53. Roche's payments to Enzo under the distribution agreement began in 1994, or, in the case of new products, when they were first sold. (Ex. 42, Togonal Decl. ¶4.)

54. Roche has paid Enzo more than $23 million under the agreement, (Ex. 42, Togonal Decl. ¶4.)

55. Roche detailed its sales of these 13 products (among others) in quarterly written reports to Enzo. (Ex. 42, Togonal Decl. ¶5-7.)

56. The 14 products listed in ECC 54(3) are not among those Enzo accuses Roche of selling for unauthorized purposes.

B. Enzo's Agreement with PE

57. PE had a written agreement with Enzo entitled "Distributorship Agreement." that took effect in 1999 and granted it rights to distribute and sell certain products, identified in Exhibit C of the Distributorship Agreement, notwithstanding Enzo patents. (Ex. 44, LeBlanc Decl., Ex. 1.)

58. PE developed, manufactured and sold the products listed on Exhibit C and paid Enzo a "transfer payment" based on the amount of product sold. (Ex. 44, LeBlanc Decl. Ex. 1 ¶14.)

59. PE terminated the agreement at the end of 2004. (Ex. 44, LeBlanc Decl. ¶¶19, 20, 21; Ex. 25, Mayer Decl. ¶36.)

60. The Ward patents expired at the end of 2004. (Ex. 9, '767 patent, Ex. 8, '824 patent.)

61. After terminating the agreement, PE ceased selling the Exhibit C products that are accused of infringing the '060 patent. (Ex. 25, Mayer Decl. ¶¶35, 36.)

62. Excepting its AcycloPrime and Micromax products, the PE products accused of infringement are all products for which PE has paid, and Enzo has accepted, more than $15 million. (Ex. 44, LeBlanc Decl., ¶12.)

63. PE labeled the products it sold as required by the agreement. (Ex. 44, LeBlanc Decl. ¶5.)

III. DEFENDANTS ARE ENTITLED TO SUMMARY JUDGMENT ON ENZO'S LANHAM ACT CLAIM.

64. The gravament of Enzo's Lanham Act claim against the defendants is that defendants were marketing "products utilizing Enzo technology covered under issued patents which is not being attributed to Enzo." (Ex. 45, Weiner Tr. at 39.)

65. Enzo's claim is thus premised on a failure to list Enzo's patents on defendants' marketing materials.

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Respectfully submitted,

/s/ Robert J. Gunther, Jr.

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